

PHARBEDRYL - diphenhydramine hcl capsule
Pharbest Pharmaceuticals, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (in each capsule)

Diphenhydramine HCl 25mg

Purpose

Antihistamine

Uses

- Temporarily relieves these symptoms associated with the common cold, hay fever, or other respiratory allergies:
- sneezing
- itching of the nose or throat
- runny nose
- itchy, watery eyes
- Temporarily relieves these symptoms due to common cold:
- runny nose
- sneezing

Warnings

Do not use

- to make child sleepy
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

- avoid alcoholic drinks
- marked drowsiness may occur

- excitability may occur, especially in children
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away 91-800-222-1222).

Directions

- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours

adults and children 12 years and above	1-2 capsules
children 6 to under 12 years	1 capsule
children under 6 years	Ask a doctor

Other information

- **Tamper Evident: Do not use if safety seal under cap is broken or missing**
- store between 20°-25°C (68°-77°F)
- protect from excessive moisture

Inactive ingredients

black iron oxide, D&C red #28, D&C blue #1, FD&C red #40, gelatin, lactose monohydrate, magnesium stearate, silicon dioxide, sodium lauryl sulfate

Questions?

Adverse drug event call (866)562-2756 Mon - Fri 8 AM to 4 PM

PHARBEST

NDC 16103-0348-11

Manufactured in the USA

*** Compare to the active ingredient in Benadryl® Ultratabs**

PHARBEDRYL

Diphenhydramine HCl 25mg

Antihistamine

- Sneezing
- Itchy, Watery Eyes
- Runny Nose
- Itchy Throat

1000 CAPSULES

THIS PACKAGE FOR HOUSEHOLD WITHOUT YOUNG CHILDREN

PHARBEST Manufactured in the **USA**
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PHARBEDRYL
 Diphenhydramine HCl 25mg
Antihistamine
 ♦ Sneezing ♦ Runny Nose
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1000 CAPSULES
 This Package for Households Without Young Children

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts
Active ingredient (in each capsule)
 Diphenhydramine HCl 25mg.....Antihistamine
Purpose
 Diphenhydramine HCl 25mg.....Antihistamine
Uses
 ■ Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ itching of the nose or throat ■ runny nose ■ itchy, watery eyes
 ■ Temporarily relieves these symptoms due to common cold: ■ runny nose ■ sneezing
Warnings
 Do not use ■ to make child sleepy ■ with any other product containing diphenhydramine, even one used on skin. Ask a doctor **before** use if you have, trouble urinating due to an enlarged prostate gland, or a breathing problem such as asthma or emphysema. ■ alcohol ■ grapefruit juice. Ask a doctor or pharmacist **before** use if you are taking sedatives or tranquilizers.
When using this product ■ avoid alcoholic drinks ■ marked drowsiness may occur ■ excitability may occur, especially in children ■ alcohol, sedatives and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery.
If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).
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Questions? Adverse drug event call (866) 562-2756 Mon - Fri 8 AM to 4 PM
This product is not manufactured or distributed by Mohell Consumer Healthcare, owner of registered trademark of Benadryl® Ultratabs®
Manufactured By:
 Pharbest Pharmaceuticals, Inc.
 14 Engineers Lane,
 Farmingdale, NY 11735
 L.Rev 04/22

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PHARBEDRYL

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16103-348
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII: 8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
D&C RED NO. 28 (UNII: 7671P0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	pink (PINK (clear) , WHITE (clear) , RED (band))	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	PH014
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16103-348-03	1 in 1 CARTON	02/01/2016	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:16103-348-08	1 in 1 CARTON	02/01/2016	
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:16103-348-11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/01/2016	

Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	analysis(16103-348) , manufacture(16103-348) , pack(16103-348) , label(16103-348)

Revised: 6/2023

Pharbest Pharmaceuticals, Inc.